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Prior Notice of Imported Food
Docket No. 2002N-0278

The German Agricultural Marketing Board – CMA, the official government trade and marketing organization representing foods and beverages from Germany, appreciates the opportunity to comment on the Interim Final Rule concerning the Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. We recognize the need to protect public health, however, not through a disruption of trade.

The Interim Final Rule has been in effect since December 12, 2003 and as a result, has given the industry an opportunity to use the new system and to find out where confusion and problems exist.

We have been extremely active in assisting the German food and beverage industry in complying with the new requirements. However, in our own personal experiences as well as those of the individual companies, massive problems seem to have constantly occurred.

Many of our US importers are small businesses dealing with small to middle-sized German manufacturers and the following topics come from these segments of the industry.

The overriding problems seem to be accessibility to the website, cost and time of the filing procedure, language barriers and complexity of the information requested.

Below are some examples of these issues and possible suggestions for their resolution, while still fulfilling the requirements of the Act.

PROBLEM: The biggest problem seems to be for mail order companies, who sometimes mail thousands of packages at one time. When you consider, that each individual package needs a prior notice, the workload becomes unbearable. Since these companies cannot afford to hire additional staff and in addition, the sheer volume of the type of information required, makes this a very overwhelming task.

SUGGESTION: Would it be possible for the manufacturers to only submit their company information and product information for similar items once and then add the different recipients' addresses at the end? At completion, either the manufacturer could receive one number for all of the shipments sent at the same time or possibly the FDA computer could generate all required separate numbers at once. This seems more cost and time efficient for all concerned.

PROBLEM: An additional huge problem encountered by our companies (and also by us when trying to assist the companies): Either we could not gain access to the website for hours on end and/or it could only be accessed on the computer that had done the initial company registration. It had been our belief that the Prior Notice could be done by anyone regardless of who submitted the company registration. And yet, when trying to gain access to the website, only the actual computer used for the registration worked. This posed problems when other departments of a company needed to submit a Prior Notice since the person who was at that particular computer had to finalize all paperwork for everyone else. In all of these scenarios, it is again time costly and inefficient.

SUGGESTION: Allow a fax option for any company that is having problems gaining access to the website. We are certain that in underdeveloped countries, the problem of accessing a computer is even more difficult than for, as in this case, a developed country (who is having a hard time!).

PROBLEM: Companies were not able to access the website for days and, as a result, not in a timely manner. One manufacturer tells of a case, where all day Friday, access was denied and that a fax submission was not possible. The shipment arrived on Sunday and no Prior Notice had been filed. The products were detained by Customs as a result and finally after much discussion, the shipment was released (cost $180 !!)

SUGGESTION: As stated above, fax transmission if computer access is not possible.

PROBLEM: Several companies told us that in order to complete the forms, several security settings on the respective computers had to be disabled. In this age of computer hackers and viruses, this action is not welcome by the companies and creates great uneasiness.

QUESTION: Would an easier solution without taking these steps be possible?

PROBLEM: Below is an accurate example of the problems encountered by one of the above-mentioned mail order companies when trying to fulfill the Prior Notice Requirements:

"In January and February, which is a rather calm business period for us, it took at least 20 minutes from the start of a web entry till finishing the Prior Notice ! Frequently occurring breakdowns of your website make us afraid of our main season in the months before Christmas and let us fear the worst case !

"Considering the fact that in this period we send up to 1.000 mail parcels per day to the US, a mere sticking to the current procedure is – already out of reasons of time – unthinkable.

THEIR SUGGESTION: "To ensure the continuation of our renowned mail order service we propose that US-Customs give us a defined quantity of registration numbers at our disposal, which we will print in ascending order onto our dispatch labels.

"During this fully automated process, a file including all data relevant for Prior Notice would be created. This file then would be transmitted electronically to CBP resp. FDA by a FTP-server.

"If requested by them, we even could print a barcode on the dispatch labels.

"Regarding the quantities of mail parcels to be sent by us to the US, you surely understand that the current procedure of a manual input of all details is just impossible to handle. This fact would persist, even if the operation time for the manual input could be halved.

"The continuation of our mail order service to the US can only be assured, if the procedure is done electronically as described above.

PROBLEM: What can a submitter do that consistently receives the web notice "WE'RE SORRY! – We are sorry for the inconvenience. Due to technical difficulties, FDA Industry Systems cannot be used at this time. We request that you revisit this web site later. We expect that the problem will be resolved shortly". However, the problem is not resolved shortly but at times, days later.

SUGGESTION: Allow for fax submission or the information to be submitted after arrival in the US (if time is short before arrival as was the case in the example cited above)

PROBLEM: In many cases, the smaller US Importers cannot afford the additional costs charged by a broker to submit the FDA information via the ABI system. It seems that larger companies are charged $10 - $15, up to $25 per entry, depending on the volume. The cost is negotiable based on the volume. This is a situation that does not come in to play for small companies because they do not have the huge quantities and as a result, do not have the "negotiating clout" that the larger companies do. As a result, they are telling their foreign supplier to submit the prior notice. Some small companies estimate, that when including website disruptions, 80 packages would take 40 – 80 hours just for Prior Notice, they are exasperated. This is totally unmanageable.

SUGGESTION: One time entries of manufacturer and product information as explained above.

PROBLEM: Language barriers are another issue, especially when trying to establish the FDA Product Code. The tutorials do not assist the foreign companies; if anything, they confuse them further. The needed information is not clear: for instance, what is "NEC-Y" under "Process Applied". The "type of packaging (ex. "commercially sterile")" etc. is confusing to say the least. We contacted the FDA support staff for clarification on behalf of several manufacturers, who just could not get through this section. It took us DAYS to help them even though the FDA Help Desk responded quickly.

Since we were only able to go to the tutorial and could not actually "walk them through it", this part of the Prior Notice became an incredibly daunting and difficult task. As an American, I found the system quite difficult and complicated to maneuver through.

SUGGESTION: Use the Customs Numbers the companies must use from the Harmonized Tariff Schedule of the United States. Without these numbers, Customs does not allow products to enter the US and we feel, they provide all the information that the FDA would need.

PROBLEM: If small and mid-sized companies are spending 40 minutes per entry for a shipment, how will "Grandmother" be able to do this when sending food as gifts to the US? What happens if Granny does not have access to a computer, which is often the case? In addition, odds are great that she also does not speak any English.
Most US consumers are still not aware of the new requirements, how can FDA expect that foreigners will know about them?

SUGGESTION: Provide a form to all Post Offices worldwide (in the native language) that could be filled out onsite and attached to the product, similar to the Customs Declaration. It would at least provide the FDA with important tracking information, should that become necessary. Keep the form short and simple (the current required information is much too cumbersome for the average consumer).

PROBLEM: Many of the express couriers refuse to do the necessary paperwork for shipments being sent via their services. This means that the manufacturers are required to submit the Prior Notice (the regulations also do not stipulate who must fill out the form). The problem is, that the manufacturer does not have any of the necessary information needed to complete the form, such as flight number, departure and arrival, etc. It becomes a "catch 22".

SUGGESTION: Treat Express Couriers (DHL, FedEx etc) the same as mail shipments to simplify the filing requirements for the submitter.

PROBLEM: We translated the Food Facility Registration Form as well as the instructions into German to facilitate compliance for our companies. We find the Prior Notice impossible to do, in first order, because we are not able to obtain a workable copy (the tutorial does not lend itself to it) and there seem to be constant changes to the system.

SUGGESTION: Provide Foreign Governments and Trade Organizations (such as ourselves) with a detailed outline of the Prior Notice Form with explanations of the individual requirements etc. so that they can be translated into the respective languages and sent out to the affected companies. The FDA would also need to keep these government agencies and groups apprised of any changes and updates as they are made. It would be a partnership towards achieving compliance for all involved.

Conclusions

We truly believe that the new regulations continue to deter the innocent from entering the market and the small and mid-size companies from keeping their market share, and we are sure that is not anyone's intention.

We appreciate the opportunity to submit our comments, suggestions and concerns and applaud the FDA for their openness and willingness to listen. The fact that the Agency issued Interim Final Rules rather than Final Rules and the FDA's reopening of the comment period, to allow for actual trade experiences, is to be commended.

We thank you for your attention to our comments and are available should you have any additional questions.

On behalf of the German Agricultural Marketing Board – CMA and small and medium-sized German food and beverage manufacturers and their US importers, I remain

Very truly yours,

German Agricultural Marketing
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